DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2006

Ms. Kelly Rowland, MA
Regulatory Affairs Specialist
Quality and Regulatory Affairs
STEREOTAXIS, INC.
4041 Forest Park Avenue
St. Louis, MO 63108

Re: K051373
Trade/Device Name: Cronus Guidewire, Model 001-001470-1
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Product Code: NDQ
Dated: November 29, 2005
Received: December 1, 2005

Dear Ms. Rowland:

This letter corrects our substantially equivalent letter of December 9, 2005

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrnd
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2: Indications for Use Statement

Statement

The indications for Use Statement:

510(k) Number: K_____

Device Name: Stereotaxis Guidewire and Stereotaxis Telstar® Magnetic Navigation System [MNS]

Stereotaxis Guidwire:
The Stereotaxis Cronus® Endovascular Guidewire is intended to introduce and position over-the-wire catheters and other over-the-wire therapeutic devices within the neurovasculature, coronary and peripheral vasculature during PTCA or other intravascular interventional procedures.

The Stereotaxis Cronus® Endovascular Guidewire is not intended for use without a Stereotaxis Magnetic Navigation System [MNS]. Rotational atherectomy devices and any ferromagnetic interventional devices are contraindicated for use with the Stereotaxis Endovascular Guidewire.

Stereotaxis Telstar® Magnetic Navigation System [MNS]:
The TMNS is intended to navigate a magnet-tipped device through tissue to designated target sites in the right and left heart, coronary, peripheral, and neurovasculature by orienting the device tip in a desired direction.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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DEC 9 2005
K051373

Appendix 1: 510(k) Summary of Safety and Effectiveness

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Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below.

For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR §807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device description

The Telstar® Magnetic Navigation System [TMNS] is an interventional workstation for the intravascular navigation of a magnetic-tipped device through tissue to designated target sites in the right and left heart, coronary, peripheral, and neurovasculature. It combines a bi-planar fluoroscopy system with a computer controlled magnetic field generator, to provide both visualization and control of a magnetically actuated guidewire. The system employs magnetic fields to *orient* the guidewire.

The Stereotaxis Cronus® Modified is a steerable guidewire that has a nominal diameter of 0.014 in/0.36 mm and a nominal length of 210 cm or 300 cm. The guidewire is designed only for use in conjunction with a Stereotaxis Telstar® Magnetic Navigation System [TMNS]. The wire is configured with a tapered distal tip and an embedded magnet, which is used for navigating the wire through the vasculature. This device is sterilized with 100% ethylene oxide.

Intended use

The Telstar® Magnetic Navigation System [TMNS] is intended to navigate a magnetic-tipped device through tissue to designated target sites in the right and left heart, coronary, peripheral, and neurovasculature by orienting the device tip in a desired direction.

The Stereotaxis Endovascular Guide Wire is intended to introduce and position over-the-wire catheters and other over-the-wire therapeutic devices within the neurovasculature, coronary and peripheral vasculature during PTCA or other intravascular interventional procedures.

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Appendix 1: 510(k) Summary of Safety and Effectiveness,
Continued

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Technological characteristics	The Telstar® Magnetic Navigation System [TMNS] employs application of magnetic fields to orient the distal tip of a magnetically actuated guidewire. The Telstar® Digital Imaging System [TIS], previously cleared under K013484 and K022565, provides visualization through standard fluoroscopy. The Cronus® Modified is a conventional 0.014" (0.36 mm) hydrophilic-coated endovascular guidewire modified to accommodate magnetic actuation and control. It is designed to navigate within the vasculature to deliver a suitable catheter or interventional device to a desired site. The finished lengths of the Cronus® Modified are between 180 and 300 cm. A taper runs 32 cm proximal to the distal tip. The pushable shaft is a continuous wire that allows axial force, applied at the proximal end, to be transmitted to the tip of the guidewire.
Performance data	Bench testing and pre-clinical and clinical *in vivo* testing demonstrate that the Stereotaxis Telstar® Magnetic Navigation System [TMNS] and the Cronus® Modified perform in an equivalent manner to the Stereotaxis Telstar® Magnetic Navigation System [TMNS], and the Stereotaxis Cronus® Predicate and the Boston Scientific TRANSEND™ EX Platinum Steerable Guide Wire predicate devices.
Conclusion	The Stereotaxis Telstar® Magnetic Navigation System [TMNS] is substantially equivalent to the Stereotaxis Telstar® Magnetic Navigation System [TMNS] (K013484) and the BrainLAB VectorVision^2 (VV^2) (K983831) predicate devices. The Stereotaxis Cronus® Modified is substantially equivalent to the Stereotaxis Cronus® Predicate (K042854) and the Boston Scientific TRANSEND™ EX Platinum Steerable Guide Wire (K971254) predicate devices.
Contact	Kelly Rowland Regulatory Specialist
Date	May 20, 2005